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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/622,635	10/12/2000	Olli Kallioniemi	4239-55278	8528

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EXAMINER	
CHAKRABARTI, ARUN K	
ART UNIT	PAPER NUMBER
1655	7

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.	Applicant(s)
09/622,635	Kallioniemi et al.
Examiner	**Art Unit**
Arun Chakrabarti	1655

-- **The MAILING DATE of this communication appears on the cover sheet with the correspondence address** --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on Mar 5, 2001 .

2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) 1-22 and 24-52 is/are pending in the application.

4a) Of the above, claim(s) _____ is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☒ Claim(s) 1-22 and 24-52 is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____ .
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

15) ☒ Notice of References Cited (PTO-892)
16) ☒ Notice of Draftsperson's Patent Drawing Review (PTO-948)
17) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). 5 and 6
18) ☐ Interview Summary (PTO-413) Paper No(s). _____
19) ☐ Notice of Informal Patent Application (PTO-152)
20) ☐ Other:

DETAILED ACTION

Election/Restrictions

1. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CAR 1.499, applicant is required, in response to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1-22 and 24-52 drawn to method of analysis of biolological specimens.

Group II, claim 23, drawn to cross-section of the biological sample cores.

Group III, claim(s) 53-79, drawn to method of constructing a specimen array.

Group IV, claim(s) 80-85, drawn to a method of screening for a disease.

2. The inventions listed as Groups I, II, III and IV do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: Claim 1 has been found to be anticipated by the prior art Stapleton et al. (U.S. Patent 6,103,192) (August 15, 2000) which clearly shows that claims of Group II, III and IV lack the same or corresponding special technical features .

3. During a telephone conversation with William Noonan (503-226-7391) on April 9, 2001, a provisional election was made with traverse to prosecute the invention of Group I, claims 1-22

and 24-52. Affirmation of this election must be made by applicant in replying to this Office action. Claims 23 and 53-85 are withdrawn from further consideration by the examiner, 37 CAR 1.142(b), as being drawn to a non-elected invention.

4. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CAR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CAR 1.48(b) and by the fee required under 37 CAR 1.17(I).

Claim Rejections - 35 USC § 112

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 2, 6, 7 and 16-22 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 2, 6, 7 and 16-22 are rejected over the recitation of the phrase, "elongated sample". It is not clear if the original sample is extended in size and shape during boring or the sample is originally elongated. It is also not clear how a liquid sample can be elongated. It is also

not clear if the elongated samples are cylindrical in shape or rectangular rod shaped or what particular shape is claimed. The metes and bounds of the claims are vague and indefinite.

Claims 31 and 34 are rejected over the improper use of Markush language. The proper Markush language, "from the group consisting of" should be used.

Claims 9, 12 and 14 are rejected over the recitation of the phrase, "clinical and/or laboratory characteristic". It is not clear how and what characteristics are assigned in the recipient array. A laboratory can be clinical as well as non-clinical. Are both of the characteristics claimed or one of them is claimed? Are these chemical or biochemical or morphological or special characteristic corresponding to disease conditions? The metes and bounds of the claims are vague and indefinite.

7. Claims 43-48 provide for the use of a method, but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

Claims 43-48 are also rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd.* v. *Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

Claim Rejections - 35 USC § 102

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless --
>
> > (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371© of this title before the invention thereof by the applicant for patent.

9. Claims 1, 3, 4, 10-15, 24-29, 32-42 and 49- 52 are rejected under 35 U.S.C. 102 (e) as being anticipated by Stapleton et al. (U.S. Patent 6,103,192) (August 15, 2000).

Stapleton et al. teach a method of parallel analysis of tissue specimens (Abstract), the method comprising :

obtaining a plurality of donor specimens (Figure 2 and Column 14, lines 35-36);

placing each donor specimen in an assigned location in a recipient array (Figure 2 and Column 14, lines 55-66);

obtaining a plurality of sections from the recipient array in a manner that each section contains a plurality of donor specimens that maintain their assigned locations (Figure 2 and Examples 4 and 5 and Column 14, lines 55-66);

performing on each section a different biological analysis using the biomarker (Examples 4 and 5);

comparing the results of the different biological analyses in corresponding assigned locations of different sections to determine if there are correlations between the results of the

different biological analyses at each assigned locations (Abstract and Examples 4 and 5 and Claim 1).

Stapleton et al. teach a method wherein the biomarker is selected by high-throughput genetic analysis (Abstract, Examples 4 and 5).

Stapleton et al. teach a method wherein the biomarker comprises a numerical alteration of a chromosome, chromosomal region, gene, gene fragment, or a locus (Examples 4 and 5 and 7).

Stapleton et al. teach a method wherein comparing the results comprises determining if there is an alteration of a gene by examining a marker for gene alteration (Examples 4 and 5 and 7).

Stapleton et al. teach a method of analyzing gene amplification for detecting a genomic target sequence that is associated with a specific genetic disorder in a tissue specimen (abstract, Examples 4 and 5 and 7), the method comprising :

screening multiple genes in a biological specimen with a nucleic acid array that detects which genes are abnormally expressed in the biological specimens (Example 5); and

screening multiple tissue specimens in a tissue array with a nucleic acid probe to detect which genes are abnormally expressed in the biological specimens (Example 5);

wherein the result of screening multiple genes is used to select the nucleic acid probe to screen the multiple tissue specimens, or wherein the result of screening multiple tissue specimens is used to select the array that detects awhich genes are abnormally expressed in the biological specimens (Example 5).

Stapleton et al. inherently teach the donor specimen from a population of tumor cells (Column 8, lines 1-13 and Example 10).

Stapleton et al. teach the different biological analyses are from at least one nucleic acid hybridization. (Example 10).

Stapleton et al. teach the method wherein the donor specimen is from breast cancer. (Column 23, lines 27-60).

Stapleton et al inherently teach the method wherein the characteristics of tumor cells are of patient age, tumor grade and tumor size as he studies the metastatic potential or drug resistance of tumors (Column 23, lines 27-60 and Column 2, lines 19-26).

Claim Rejections - 35 USC § 103

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CAR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later

invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103© and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

11. Claims 1-15, 24-30, 32-42 and 49-52 are rejected under 35 U.S.C. 103 (a) over Stapleton et al. (U.S. Patent 6,103,192) (August 15, 2000) in view of Furmanski et al. (U.S. Patent 4,914,022) (April 3, 1990).

Stapleton et al. teach the method of claims 1, 3, 4, 10-15, 24-29, 32-42 and 49- 52 as described above.

Stapleton et al. do not each the method wherein the donor specimen is obtained by boring an elongated sample from the donor specimen which is placed in the assigned location in the recipient array to form an elongated receptacle of the recipient block and obtaining a plurality of copies comprising sectioning the array transverse to the elongated donor specimen.

Furmanski et al teach the method wherein the donor specimen is obtained by boring an elongated sample from the donor specimen which is placed in the assigned location in the recipient array to form an elongated receptacle of the recipient block and obtaining a plurality of copies comprising sectioning the array transverse to the elongated donor specimen. (Figures 1A-F, Column 4, lines 1-6, and claims 1 and 5).

Stapleton et al. do not each the method wherein the diameter of the elongated receptacle is substantially the same as the diameter of the donor specimen.

Furmanski et al teach the method wherein the diameter of the elongated receptacle is substantially the same as the diameter of the donor specimen (Figures 1A-1F).

Stapleton et al. do not teach the method wherein the elongated donor sample core is substantially cylindrical core that has a diameter that is less than about 1 mm.

Furmanski et al teach the method wherein the elongated donor sample core is substantially cylindrical core that has a diameter that is less than about 1 mm. (Column 4, lines 17-20).

It would have been *prima facie* obvious to one having ordinary skill in the art at the time the invention was made to substitute and combine the method of preparing multiple tissue samples based on the preparation of elongated sample of Furmanski et al. in the method of Stapleton et al., since Furmanski et al. state, "Advantages of the present invention include greatly enhanced efficiency and speed for tissue testing; greatly decreased cost for multiple tissue testing; great economies in the use of test samples, reagents and test materials such a antibodies; great flexibility and ease of constructing multitissue samples of interest; greatly increased ease in scoring tissue reactivities; ability to combine screening and characterization selection of reagents of interest; ability to select regions of interest for testing from heterogeneous tissue samples (Column 2, lines 45-54)." By employing scientific reasoning, one ordinary artisan would have combined the preparation of elongated sample in the method of parallel analysis of biological specimen of Stapleton et al. to carry out an efficient and economic comparative study of the expression of different oncogenes. An ordinary practitioner would have been motivated to substitute and combine the method of preparing multiple tissue samples based on the preparation of elongated sample of Furmanski et al. in the method of Stapleton et al. in order to achieve the

express advantages noted by Furmanski et al. of an invention that include greatly enhanced efficiency and speed for tissue testing; greatly decreased cost for multiple tissue testing; great economies in the use of test samples, reagents and test materials such a antibodies; great flexibility and ease of constructing multitissue samples of interest; greatly increased ease in scoring tissue reactivities; ability to combine screening and characterization selection of reagents of interest; ability to select regions of interest for testing from heterogeneous tissue samples.

12. Claims 1, 3, 4, 10-15, 24-29, 31-42 and 49- 52 are rejected under 35 U.S.C. 103 (a) over Stapleton et al. (U.S. Patent 6,103,192) (August 15, 2000) in view of Leveen et al. (Experimental Cell Research, (1993), Vol. 207, pages 283-289).

Stapleton et al. teach the method of claims 1, 3, 4, 10-15, 24-29, 32-42 and 49- 52 as described above.

Stapleton et al. do not teach the analyses of PDGFB gene.

Leveen et al teach the analyses of PDGFB gene in cancerous cells (Abstract and Introduction, page 283, column 2, lines 1-14 and Figures 1-7).

It would have been *prima facie* obvious to one having ordinary skill in the art at the time the invention was made to substitute and combine the PDGFB oncogene study of Leveen et al. in the method of Stapleton et al., since Leveen et al. state, "Moreover, many human tumor cell types frequently express PDGFA and PDGFB mRNA and protein; rather, structurally normal PDGF genes are frequently found to be constitutively expressed in tumor cells (Page 283, Column 2, lines 5-11)." By employing scientific reasoning, one ordinary artisan would have combined the

study of PDGFB oncogene in the method of parallel analysis of biological specimen of Stapleton et al. to carry out a better comparative study of the expression of different oncogenes. An ordinary practitioner would have been motivated to combine the PDGFB oncogene study of Leveen et al. in the method of Stapleton et al., in order to achieve the express advantages noted by Leveen et al. of genes that are frequently found to be constitutively expressed in tumor cells.

Conclusion

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Arun Chakrabarti, Ph.D., whose telephone number is (703) 306-5818. The examiner can normally be reached on 7:00 AM-4:30 PM from Monday to Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Jones, can be reached on (703) 308-1152. The fax phone number for this Group is (703) 305-7401.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Arun kr. Chakrabarti

Arun Chakrabarti,

Patent Examiner,

December 3, 2001